

REMARKS

I. Preliminary remarks

New claim 12 is added herein. Support for an external preparation (i.e., composition) comprising PEG having a degree of polymerization of 45,000 can be found throughout the application as filed. See, for example, at page 6. Accordingly, no new matter has been added.

II. The rejection under 35 U.S.C. § 103(a) should be withdrawn.

The Examiner rejected claims 1 and 5-11 as allegedly being unpatentable over Trigg et al. (U.S. Patent Application Publication No. 2005/0013784) in view of Murad (U.S. Patent No. 6,800,292) and Norton (U.S. Patent No. 5,976,556). Applicant requests reconsideration of the rejection in view of the following remarks.

A. The combined teachings of the cited art fail to disclose or suggest a composition comprising polyethylene glycol (PEG) within the claimed range and having the specific pH range recited in independent claim 1.

None of the cited art discloses or suggests compositions comprising PEG within the claimed range (or polyvinyl alcohol), glycolic acid and having a pH of 2.0 or less.

The Examiner relies on Trigg as teaching a composition comprising PEG within the claimed range. Trigg, however, fails to disclose or suggest that such composition has a pH of 2.0 or less, which is a required element of claim 1. For example, see paragraph [0106] of Trigg which indicates that the pH of its composition is preferably from about 4 to about 8, which is clearly outside the pH range recited in amended claim 1. The subsequent discussion in paragraph [106] about adjustment of pH for optimum efficacy would have been understood by a reader of ordinary skill to refer to adjustment *within the specified range* of about 4 to 8 pH. It should be emphasized that pH is a (negative) logarithmic measurement, so pH of 4 has a *100-fold* lower concentration of H⁺ than pH of 2.

With respect to combining references, the Examiner asserts that it is generally *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The Applicant disagrees with this generality, as there are numerous

known instances where the combination of two or more agents which are separately useful for the same purpose is known to be detrimental. For example, combinations of two or more useful anti-inflammatory drugs can cause dangerous bleeding.

Moreover, the “same purpose” rationale does not apply to Trigg and the other references, because they specify *different* purposes. For purposes of optimizing pH or selecting PEG or any other purpose, it is important to note that Trigg’s purpose was NOT exfoliation. In fact, Trigg explicitly teaches that treatment masks such as Trigg’s can be distinguished from “removal” masks. (See Trigg paragraph [0003], for example. Trigg teaches a treatment mask.

The teachings of Murad and Norton fail to remedy the deficiencies of Trigg (i.e., a composition having a pH of 2.0 or less). Murad discloses that its composition(s) comprise(s) at least one fruit extract¹ and a moisturizing agent. Murad fails to disclose or suggest a composition comprising glycolic acid and polyethylene glycol (PEG), wherein the PEG has a polymerization degree of 2,000 to 50,000. Murad generically discloses that its compositions may contain PEG and specifically discloses PEG-100, which is clearly outside of the range recited in claim 1 (i.e., PEG-2,000 - PEG-50,000).² Murad is silent with respect to the pH of its composition. Thus, Murad cannot be relied upon as teaching a composition having a pH of 2.0 or less.

As noted above, the purpose of Trigg was related to a treatment mask, which Trigg teaches can be distinguished from a removal mask. Norton, in contrast, teaches a purpose of exfoliation. It would not be obvious to look to Trigg for a way to modify or improve any composition found in Norton. Moreover, with respect to pH, Norton appears to prefer a pH in the range of 2.5 to 4.5, which would constitute a teaching away from the lower range recited in the Applicant’s claims. If one were to combine the teachings of Norton with any other teachings for the purpose of an improved composition, it would be unobvious to deviate from Norton’s preferred pH.

¹ The claims of the present invention do not require a fruit extract.

² In this regard, the Examiner’s allegation at pp. 3-4 of the action that a polymerization degree of from 2000-50000 is obvious of any polyethylene glycol in the Murad preparation is entirely without support, is contrary to the only express teachings in the documents, and contrary to the understanding in the art relating to the properties of different PEG’s, as discussed more fully below.

Norton also contains teachings away with respect to the PEG component of the claimed composition. Norton generically discloses that its compositions may comprise ethylene glycol and specifically discloses PEG-40 and PEG-75. One of ordinary skill in the art would not be motivated to substitute the PEG of Trigg for the PEG-40 or PEG-75 of Norton to arrive at the claimed invention because PEG of varying degrees of polymerization have different functions, and because the compositions disclose in Norton and Trigg have different purposes.

As discussed in response to previous Office actions, PEG having a degree of polymerization below 100 (e.g., PEG-40 and PEG-75) functions as a humectant and/or a solvent while a PEG having a degree of polymerization 2,000 or greater functions as an emulsion stabilizer and/or a viscosity increasing agent. See, ICID and Handbook, 11th Edition (2006), pages 1549-1635 set forth in Appendix A. It is also known in the art that PEGs with varying degrees of polymerization are provided in different forms. For example, PEG having a degree of polymerization less than 420 is provided as a liquid, while PEG having a degree of polymerization greater than 570 is provided in a solid form. See, Aldrich Handbook of Fine Chemicals (2007-2008), page 2023 set forth in Appendix B. The Examiner has neither pointed to a specific teaching in the cited art nor provided findings of fact concerning the state of the art that would motivate one of skill in the art to replace a PEG provided in a liquid form for use as a humectant and/or solvent, such as the PEG-40, -75 or -100 disclosed in Norton, for a PEG provided in a solid form for use as an emulsion stabilizer and/or viscosity increasing agent, such as the PEG-2000 or greater disclosed in the present application.

Moreover, experiments performed after the filing date of this application confirm that compositions comprising PEG having a degree of polymerization within the range recited in claim 1 and having a pH of 2.0 or less is superior to (i.e., more effective than) the compositions of the cited art. Submitted herewith is a Rule 132 declaration of Dr. Akinori Hanano which provides experimental data indicating that a composition comprising PEG having a degree of polymerization outside the range recited in claim 1 is inferior to the external preparation recited in claim 1. The results indicated that three different compositions comprising varying degrees of polymerization of PEG within the range recited in claim 1 (i.e., PEG-2,000, PEG-7,000 and PEG-45,000) were more effective than a composition

comprising PEG comprising a degree of polymerization well below the range recited in claim 1 (i.e., PEG-400). The results also indicate that a composition comprising PEG within the claimed range, but having a pH greater than 2.0 is less effective at chemically peeling the skin as the external preparation recited in claim 1.

In view of the foregoing, it is clear that the cited art fails to disclose or suggest the combination of each element (i.e., a composition comprising PEG having a degree of polymerization of 2,000 to 50,000 and having a pH of 2.0 or less) of independent claim 1. In fact, as noted above, the cited art contains teachings that would dissuade a person of ordinary skill from attempting to combine the references at all, or from selecting values within the claims, even if the Examiner's combination of references were made. Moreover, because the combined teachings of the cited art fail to disclose or suggest each and every element of the claims, there can be no reasonable expectation of successfully arriving at the claimed invention. Thus, the rejection of claim 1 and those claims dependent thereon under 35 U.S.C. § 103(a) should be withdrawn.

B. None of the cited art discloses or suggests a specific composition comprising polyvinyl alcohol and glycolic acid.

Turning now to the rejection of independent claim 6, Applicant disagrees with the Examiner's conclusion that the combined teachings of the cited art render this claim and those claims dependent thereon obvious. The Examiner has not pointed to a teaching in Trigg, Murad, or Norton that discloses or suggests a specific composition comprising glycolic acid and polyvinyl alcohol, much less a composition comprising those specific components and having a pH of 2.0 or less. For example, Trigg discloses that its composition may include *nicotinyl alcohol esters* of glycolic acid, but does not disclose or suggest the use of glycolic acid *per se* in its composition. See, paragraph [0126] of Trigg. Moreover, Trigg discloses that its composition includes a water-soluble thickening agent selected from a laundry list of more than forty-five (45) water-soluble thickening agents, one of which is polyvinyl alcohol. Again, Trigg discloses that its compositions have a pH of preferably 4 to 8, which is clearly outside the range recited in claim 6.

Murad discloses that its composition comprises at least one fruit extract and a mono- or poly-hydroxy acid selected from a laundry list of at least eighty (80) mono- or poly-

hydroxy acids (col. 9, line 36 through col. 10, line 11), one of which is glycolic acid, and a pharmaceutically acceptable carrier selected from a laundry list of at least seventy (70) different possible carriers, one of which is polyvinyl alcohol. Murad does not specifically disclose a composition that comprises glycolic acid and polyvinyl alcohol and provides absolutely no teaching or suggestion that would motivate one of skill in the art to select the specific components recited in claim 6 from the *thousands* of combinations that could be made from mixing and matching different elements from these laundry lists of agents. Murad also provides no guidance as to why one of skill in the art would substitute the pharmaceutically-acceptable carrier provided in the exemplified compositions of Murad comprising glycolic acid (see Examples 5, 6 and 8-10) with polyvinyl alcohol.

Norton discloses that its composition comprises an acid protease³ and an acidic buffer. Norton discloses that the acidic buffer includes one of at least twelve (12) acids (col. 10, lines 41-44), one of which is glycolic acid, and a pharmaceutically-acceptable carrier selected from at least nine (9) pharmaceutically acceptable carriers (col. 10, lines 63-65), one of which is polyvinyl alcohol, but does not specifically disclose a composition that specifically comprises glycolic acid and polyvinyl alcohol. In fact, none of the compositions exemplified in Norton contain either of these components. See Tables III-X of Norton. As already noted, Norton appears to prefer a pH of 2.5 to 4.5, which exceeds (and teaches away from) the lower pH recited in claim 6.

Because none of the cited art specifically discloses or suggests a composition comprising glycolic acid and polyvinyl alcohol, there can be no reasonable expectation of successfully arriving at the claimed invention. Thus, the rejection of claim 6 and those claims dependent thereon under 35 U.S.C. § 103(a) should be withdrawn.

C. None of the cited art discloses or suggests a composition comprising polyethylene glycol having a degree of polymerization of 45,000.

New claim 12 recites an external preparation (i.e., composition) comprising glycolic acid and polyethylene glycol (PEG), wherein the PEG has a polymerization degree of 45,000, which is neither disclosed nor suggested by any of the cited references. Thus, claim 12 is

³ The claims of the present invention do not require an acid protease.

allowable over the cited art for this additional reason. Also, as noted in the accompanying Rule 132 declaration, the PEG 45,000 had the best properties of various tested compositions.

III. Conclusion

No other fees are believed to be due with the filing of this paper. However, the Director is authorized to charge any additional fees deemed necessary to Deposit Account No. 13-2855, under order number 19036/40139. If the Examiner believes that a telephone conversation would expedite allowance of the claims, he is invited to contact the undersigned agent at the number below.

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Respectfully submitted,

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